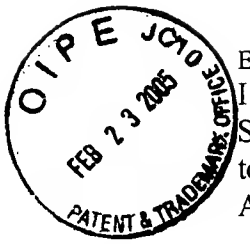

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CURTIS SCHRAMM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Gotwals, et al.
Application No.:	09/996,738
Filed:	November 30, 2001
Title:	METHOD FOR THE TREATMENT OF INFLAMMATORY DISORDERS
Group Art Unit:	1644
Examiner:	Maher Haddad, Ph.D.

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF BRIEF ON APPEAL

Sir:

The attached Brief on Appeal is submitted in furtherance of the Notice of Appeal filed in the above-identified application on September 17, 2004. Three copies of the Brief on Appeal are submitted herewith. A check in the amount of Five Hundred Dollars ($500.00) in payment of the fee for filing a Brief on Appeal by a large entity, and a Petition for Extension of Time and check for the requisite fee, are also attached.

Respectfully submitted,

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Date: February 22, 2005

Please charge any additional fees due in connection with this communication to Deposit Account No. 04-0838. A copy of this Transmittal is enclosed for deposit account charging purposes.

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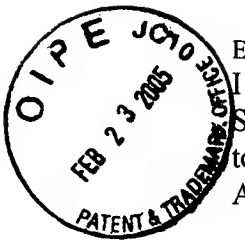
Docket No. A076US



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Alexandria, VA 22313-1450

BRIEF ON APPEAL

This Brief on Appeal is submitted in furtherance of the Notice of Appeal filed in the above-identified application on September 17, 2004. The accompanying Transmittal of Brief on Appeal details the submission of the requisite copies, fees, and petition for extension of time.

I. The Real Party in Interest.

The real party in interest in this Appeal is Biogen Idec MA Inc., the owner by assignment of the above-identified application on appeal.

II. Related Appeals and Interferences.

On information and belief, there are no cases currently on appeal before the Board which may have a bearing on the Board's decision in the instant Appeal.

III. Status of Claims.

Claims 1-7: are pending, were finally rejected in the March 23, 2004 Office Action issued in the instant application, and are on appeal. Claims 1-7 as finally rejected are set forth in the Claims Appendix.

Claim 1 is the only independent claim; claims 2-7 depend from claim 1. With respect to the issues on appeal, claims 2-7 are deemed to stand or fall together with claim 1.

Claims 1-7 stand as finally rejected under 35 U.S.C. § 112, ¶ 1 as described hereinafter.

Claims 1-7 also stand as finally rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over the prior art as described hereinafter.

IV. Status of Amendments.

No Amendments were filed after the final Office Action. All Amendments have been entered.

V. Summary of Claimed Subject Matter .

Appellants' claimed invention relates to methods for the treatment of arthritis comprising administering to a subject suffering from arthritis a composition comprising a function blocking antibody or a fragment thereof which binds to an epitope of VLA-1 consisting of the amino acids Val-Gln-Arg-Gly-Gly-Arg (SEQ ID NO: 8 of the application) or equivalents of that sequence, and wherein the function blocking antibody or a fragment thereof is administered to the subject in a dosage of between about 10 mg to about 250 mg and over a dosing period of between about one to about seven days to provide a decrease in arthritic score of about 65% or greater when compared to a control antibody treated subject.

VI. Grounds of Rejection to be Reviewed on Appeal.

Whether claims 1-7 are unpatentable under 35 U.S.C. § 112, ¶ 1 on grounds that the terms "equivalents thereof" and "a dosage of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days" in claim 1 constitute new matter which was not described in the specification of the application as originally filed.

Whether claims 1-7 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over U.S. Patent No. 5,788,966 ('966 Patent).

Whether claims 1-7 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over the '966 Patent in view of Riikonen *et al., Biochemical and Biophysical Research Communication* 209:205-212 (1995)("*Riikonen*") and further in view of Fabbri *et al., Tissue Antigens* 1996: 48; 47-51("*Fabbri*").

Whether claims 1-7 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over the '966 Patent in view of *Riikonen*.

VII. Argument.

1. The Rejection of Claims 1-7 Under 35 U.S.C. § 112, ¶ 1.

Appellants traverse the rejection of claims 1-7 under 35 U.S.C. § 112, ¶ 1, and maintain that the terms "equivalents thereof" and "a dosage of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days" in claim 1 do not constitute new matter as they were inherently contained in the specification of the application as originally filed.

(a) The Examiner Applied an Improper *Ipsis Verbis* Standard.

The Examiner improperly applied an "*ipsis verbis*" standard in finding that claims 1-7 contained new matter. *See* March 23, 2004 Office Action at p. 2. Whether or not particular subject matter in a claim constitutes new matter is not evaluated on the basis of whether the subject matter is described *ipsis verbis* in the application as originally filed.

Instead, the fundamental inquiry is whether the subject matter at issue was inherently contained in the original application. *See Schering Corp., et al. v. Amgen Inc.*, 222 F.3d 1347, 55 U.S.P.Q.2d 1650 (Fed. Cir. 2000). As explained in the following section, there was inherent support in the specification of the instant application as originally filed for the claim 1 terms "equivalents thereof" and "a dosage of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days".

(b) <u>The Original Application Inherently Disclosed the Terms at Issue</u>.

The application as originally filed disclosed that in a preferred embodiment, antibodies used in the claimed methods bound to an α1-I domain epitope which included the amino acids Val-Gln-Arg-Gly-Gly-Arg (SEQ ID NO: 8)(*see* page 9, lines 9-13). In his new matter rejection, the Examiner maintained that the application as originally filed did not disclose antibodies to the SEQ ID NO: 8 epitope. March 23, 2004 Office Action at p. 2. This contention was incorrect: Examples 15 and 18 of the application as originally filed described an antibody which bound to SEQ ID NO: 8 and also described how to identify useful antibodies which would bind to equivalents of that sequence.

Example 18 of the application as originally filed disclosed that monoclonal antibody (mAb) AJH10 bound to the SEQ ID NO: 8 epitope. Further, Example 15 of the application as originally filed illustrated how to identify α1β1 (VLA-1) function blocking antibodies which could be used in the claimed methods and which would target a human α1-I domain epitope corresponding to SEQ ID NO: 8 or equivalents thereof.

The above-cited excerpts from the application as originally filed made it clear to those of ordinary skill in the art that the claimed invention encompassed the use of antibodies which targeted functional equivalents of SEQ ID NO: 8. Those of ordinary skill in the art as of the effective filing date of the application would have had no doubt from the originally-filed application that the Appellants were in possession of antibodies which targeted the SEQ ID NO: 8 epitope and equivalents thereof and which could be used in the claimed methods of treatment.

Skilled artisans would have understood from the description of SEQ ID NO: 8 as a preferred epitope sequence, and the functional identification of useful antibodies

described in Example 15, that antibodies which could be used in the claimed methods of treatment included those that targeted equivalents of SEQ ID NO: 8. Taken together, Example 18 of the application as originally filed disclosed to skilled artisans which α1-I domain epitope to target and Example 15 of the application as originally filed showed skilled artisans how to make antibodies which would bind to that epitope and its functional equivalents.

Further, the dosage ranges recited in claims 1-7 fall within the dosage ranges specified in the application as originally filed, e.g., at page 19, lines 3-8. For a person of average weight, a dosage regimen of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days falls within the preferred dosage range of 0.1 to 50 mg /kg body weight administered over one to fourteen days disclosed in the application as originally filed. For example, using the dosage range in the application as originally filed, a one hundred fifty pound (sixty-eight kilogram) patient would receive 6.8 mg to 3,400 mg over one to fourteen days, which includes the dosage range of claim 1 at issue (between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days).

Accordingly, claims 1-7 cover no more than what the specification supported at the time of filing and do not contain new matter. *Schering, supra.* The Examiner's new matter rejection of claims 1-7 under 35 U.S.C. § 112, ¶ 1 was improper and should be reversed.

2. <u>The Rejections of Claims 1-7 Under 35 U.S.C. § 103(a)</u>.

Claims 1-7 stand rejected as being unpatentable as obvious under 35 U.S.C. § 103(a) over: (1) the '966 Patent; (2) the '966 Patent in view of *Riikonen* and further in view of *Fabbri*; and (3) the '966 Patent in view of *Riikonen.*

Appellants traverse each of these rejections of claims 1-7 under 35 U.S.C. § 103(a) and maintain that claims 1-7 are patentable over the '966 Patent; the '966 Patent in view of *Riikonen* and further in view of *Fabbri*; and the '966 Patent in view of *Riikonen.*

Appellants further maintain that the Examiner failed to establish a *prima facie* case of obviousness for any of the claims on appeal.

As explained in detail hereinafter, the '966 Patent, whether taken alone or in combination with *Riikonen* and/or *Fabbri*, does not render the claims on appeal unpatentable as obvious.

(a) Claims 1-7 Are Patentable Over The '966 Patent.

(i) The '966 Patent.

The '966 Patent discloses an antibody mAb 1B3.1 which forms a complex with, and inhibits collagen binding to, VLA-1. Additionally, the '966 Patent discloses that the synovial fluid of arthritis patients expresses enhanced levels of VLA-1 ('966 Patent; column 8, lines 64-67). One embodiment of the invention claimed in the '966 Patent relates to the treatment of disorders associated with elevated levels of VLA-1 ('966 Patent; column 5, lines 12-14).

Neither this disclosure nor any other aspect of the '966 Patent renders claims 1-7 unpatentable as obvious, as explained hereinafter.

(ii) The Examiner Failed to Establish a *Prima Facie* Case of Obviousness.

A *prima facie* case of obviousness is only established where the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rijckaert*, 9 F.3d 1531, 28 U.S.P.Q.2d 1955 (Fed. Cir. 1993). The following sections explain in detail: (1) why the '966 Patent would not have suggested the methods of treatment of the appealed claims to those of ordinary skill in the art as of the effective filing date of the appealed claims; and (2) how the Examiner erred in his analysis of the obviousness of the appealed claims in view of the '966 Patent.

(iii) The Examiner Did Not Analyze the Obviousness of the Claimed Invention When Taken as a Whole and Misconstrued or Ignored Distinguishing Claim Limitations.

Obviousness must be assessed by analyzing the claimed invention when taken as a whole, rather than by focusing on the obviousness of particular substitutions and differences. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). Claim limitations cannot be ignored in assessing obviousness, *id.*, and obviousness rejections must be supported by sound scientific theory. *See* MPEP 2144.02. These controlling legal principles were ignored by the Examiner when he interposed his obviousness rejections.

The Examiner maintained that the mAb described in the '966 Patent - mAb1B3.1 - was the same as the antibodies recited in the claimed methods of treatment and that the dosage regimen and therapeutic endpoint limitations of the claims on appeal were a mere optimization of ranges and endpoints in the '966 Patent. *See* March 23, 2004 Office Action at p. 3; October 21, 2003 Office Action at pp. 3-4. Thus, the premise of the Examiner's obviousness rejections was that the '966 Patent taught the "same method of treatment" as the method of treatment of the appealed claims. *See* March 23, 2004 Office Action at p. 3. This premise was incorrect, as it: (1) ignored limitations of claims 1-7 which were not found in the prior art; and (2) lacked scientific support.

On best present information, there is no basis to conclude that the epitope of the antibodies used in the methods of the appealed claims encompasses the mAb 1B3.1 epitope, such that those antibodies could be considered the same as mAb 1B3.1. The '966 Patent and other prior art of record belie the Examiner's assumption that the methods of the claims on appeal and those of the '966 Patent administered the same treatment.

The '966 Patent indicated that not all VLA-1 antibodies target the same epitope and stressed that mAb 1B3.1 bound to a different epitope than the known VLA-1 antibody TS2/7. *See* '966 Patent; column 8, lines 42-46. Kern, *et al., The Journal of Biological Chemistry,* Vol. 269, No. 36, pp. 22811-22816 (1994)(*Kern*)(cited

in the June 4, 2002 Information Disclosure Statement submitted in the application on appeal) also illustrates that as of the effective filing date of the instant application, skilled artisans had no basis to conclude that the epitope of mAb 1B3.1 was defined by SEQ ID NO: 8.

Kern analyzed the binding of mAb 1B3.1 to the α1 I- domain. While the human α1 I- domain disclosed in Figure 2 of *Kern* includes the amino acid sequence of SEQ ID NO: 8, *Kern* did not specify that mAb 1B3.1 bound to an epitope within the human α1 I- domain which included the amino acid sequences of SEQ ID NO: 8 or equivalents thereof. Those of ordinary skill in the art as of the effective filing date of the instant application may have understood that all VLA-1-blocking mAb's recognized the α1 I- domain, but they did not understand that all such antibodies necessarily bound to an epitope comprising SEQ ID NO: 8 or equivalents thereof.

The '966 Patent also failed to disclose the dosage and arthritic score therapeutic endpoint limitations of the claims on appeal. In fact, the '966 Patent failed to disclose any dosage regimen or therapeutic endpoints whatsoever and there is no support for the Examiner's contention that a dosage regimen of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days constituted a routine modification of dosage regimens used in equivalent treatments. *See Rijckaert, supra* (unsubstantiated assertion that claim limitation was well-known in the prior art was improper as the limitation was not found in the prior art at issue).

In summary, the Examiner's positions that the '966 Patent taught the "same method of treatment" as the methods of treatment of the appealed claims, and that the appealed claims reflect nothing more than routine substitutions or optimizations of known prior art features, was scientifically unsound and ignored distinguishing claim limitations. Accordingly, the Examiner's rejection of the appealed claims as being obvious over the '966 Patent was improper and should be reversed.

(b) Claims 1-7 Are Patentable Over The '966 Patent In View of *Riikonen* and Further In View of *Fabbri*.

(i) *Riikonen* and *Fabri*.

In April 1995, *Riikonen* disclosed that the mAb SR-84 was specific for the human α1-1 integrin subunit and completely blocked the adhesion of HeLa cells to Type IV collagen. *Riikonen* also disclosed that VLA-1 is expressed in the synovial lymphocytes of patients with rheumatoid arthritis. The *Riikonen* authors summarized their findings as showing "that α1β1 can discriminate between different types of collagens and regulate the ability of cells to adhere to their surroundings." *Riikonen* at p. 211.

Thereafter, in July 1996, *Fabbri*: (1) disclosed that the FB12 mAb blocked the adhesion of activated T lymphocytes to collagen type (IV); (2) concluded that the FB12 mAb "may represent a useful reagent for the study of the biological function of α1-1 integrin I domain"; and (3) stated that the disclosed results "suggest that the α1-1 domain has a functional role in lymphocyte binding to ECM proteins, including FN." *Fabbri* at pp. 48, 50.

(ii) The Examiner's Rejection Based On the '966 Patent, *Riikonen* and *Fabri*.

The Examiner maintained that the fact that *Fabbri* disclosed that the FB12 mAb blocked the adhesion of activated T lymphocytes to collagen type (IV) and *Riikonen* disclosed that VLA-1 is expressed in the synovial lymphocytes of patients with rheumatoid arthritis provided the requisite motivation for skilled artisans to substitute *Fabbri's* FB12 mAb for the '966 Patent mAb 1B3.1 in the methods disclosed in the '966 Patent. *See* March 23, 2004 Office Action, pp. 4-5; October 21, 2003 Office Action, pp. 5-6.

(iii) The Examiner Failed to Establish a *Prima Facie* Case of Obviousness.

In order for the Examiner to have established a *prima facie* case of obviousness based on the '966 Patent, *Riikonen*, and *Fabri*, he needed to show that, prior to the effective filing date of the claims on appeal: (1) there was a suggestion or motivation that would have led those of ordinary skill in the art to modify and combine the disclosures of the '966 Patent, *Riikonen*, and *Fabbri* in the manner he advocated in his rejections; (2) there was a reasonable expectation that such modifications and combinations would

prove successful; and (3) the '966 Patent, *Riikonen*, and *Fabbri* disclosed all of the limitations of the claims at issue. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 65 U.S.P.Q.2d 1961, *reh'g en banc denied*, 2003 U.S. App. LEXIS 11897 (Fed. Cir. May 28, 2003); *Hybritech*, *supra*.

As explained in the following sections, the Examiner failed to establish any of the bases needed to support his obviousness rejection based on the '966 Patent, *Riikonen*, and *Fabbri*.

(1) <u>There Was No Motivation To Combine and Modify the Prior Art</u>.

There is no evidence that the *Riikonen* authors concluded that the mAb SR-84 could be used in the treatment of arthritis. Nor is there any evidence that *Riikonen* led the *Fabbri* authors to conclude that FB12 mAb could be substituted for mAb 1B3.1 and used to treat arthritis in the methods described in the '966 Patent.

Riikonen merely concluded that SR-84 was a valuable tool to study α1 integrin-related functions and that α1β1 discriminated against different types of collagens and regulated cell adhesion. *See Riikonen*, pp. 205, 208. *Fabri* was similarly equivocal and conjectured that FB12 might be a useful reagent for the study of the biological function of the α1-integrin I domain. *See Fabri* at p. 50. Neither *Riikonen* nor *Fabri* considered using α1-I domain antibodies to treat α1β1 integrin-related disorders.

Further, there are no facts of record which support the notion that skilled artisans would have perceived any advantage in making the combination advocated by the Examiner. For example, there is no prior art of record which compared the efficacy of FB12 mAb and mAb 1B3.1 in an arthritis model, or which otherwise provided an impetus to skilled artisans to use FB12 mAb in a method disclosed in the '966 Patent.

(2) <u>There Was No Reasonable Expectation of Success</u>.

As of the effective filing date of the application on appeal, those of ordinary skill in the art would not have reasonably expected that the combination of the '966 Patent, *Riikonen*, and *Fabbri* advocated by the Examiner would have yielded a successful method of treatment which satisfied all of the limitations of the claims on appeal. For

example, skilled artisans would not have any basis from the prior art at issue to predict that the FB12 mAb would bind to the SEQ ID NO: 8 epitope or equivalents thereof.

(3) The Limitations of the Appealed Claims are Not Found in the Prior Art.

Even if skilled artisans were motivated to combine the '966 Patent, *Riikonen*, and *Fabbri* as suggested by the Examiner, the only way the epitope, dosage regimen, and therapeutic endpoint limitations of the claims on appeal could be imported into that combination would be the improper hindsight use of the invention of the appealed claims as a template. *In re Kotzab*, 217 F.3d 1365, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000). Those distinguishing claim limitations cannot be read into the prior art if the prior art does not disclose or suggest them. *Rijckaert, supra.*

Therefore, the Examiner failed to establish a *prima facie* case of obviousness of the appealed claims based on the '966 Patent in view of *Riikonen* and further in view of *Fabbri*. The methods of treatment of the claims on appeal, when considered as a whole, are nonobvious over the '966 Patent in view of *Riikonen* and further in view of *Fabbri*.

(c) Claims 1-7 Are Patentable Over The '966 Patent In View of *Riikonen*.

(i) The Examiner's Rejection Based On the '966 Patent and *Riikonen*.

The Examiner rejected claims 1-7 as being obvious over the '966 Patent in view of *Riikonen*. Per the Examiner, *Riikonen's* disclosure that the mAb SR-84 was specific for the human α1-1 integrin subunit and completely blocked the adhesion of HeLa cells to Type IV collagen, and further disclosure that VLA-1 is expressed in the synovial lymphocytes of patients with rheumatoid arthritis, provided a sufficient motivation for skilled artisans to substitute mAb SR-84 in the methods of the '966 Patent. Additionally, the Examiner, without any explanation, maintained that skilled artisans would have had a reasonable expectation that the combination of the '966 Patent and *Riikonen* would prove successful. *See* March 23, 2004 Office Action, pp. 5-6; October 21, 2003 Office Action, pp. 6-7.

(ii) The Examiner Failed to Establish a *Prima Facie* Case of Obviousness.

Prior to the effective filing date of the claims on appeal, there was no suggestion or motivation that would have led those of ordinary skill in the art to modify and combine the disclosures of the '966 Patent and *Riikonen* in the manner suggested by the Examiner, nor was there a reasonable expectation that such modifications and combinations would prove successful. *Boehringer Ingelheim Vetmedica, supra.* Even if the '966 Patent and *Riikonen* could be combined as advocated by the Examiner, the resultant combination would not satisfy the limitations of the claims on appeal.

As explained above, *Riikonen* did not conclude that SR-84 could be used to treat arthritis and there is no evidence of any suggestion or motivation which would have led skilled artisans to substitute SR-84 in the methods described in the '966 Patent. Prior art including *Riikonen* did not compare mAb 1B3.1 in an arthritis model with SR-84 or suggest in any way that SR-84 should be employed in a method disclosed in the '966 Patent. And, even if skilled artisans were motivated to combine the '966 Patent and *Riikonen* in the manner advocated by the Examiner, they would not have had a reasonable expectation that SR-84 would bind to the SEQ ID NO: 8 epitope or equivalents thereof, as required by the invention of the claims on appeal.

In light of all of the foregoing, the methods of treatment of the claims on appeal, when considered as a whole, are nonobvious over the '966 Patent in view of *Riikonen* and the Examiner's position to the contrary was in error.

VIII. Conclusion.

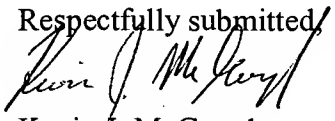
Claims 1-7 satisfy the statutory criteria of 35 U.S.C. § 112, ¶ 1. The terms "equivalent thereof" and "a dosage of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days" in claim 1 do not constitute new matter which was not described in the specification of the application as originally filed.

Claims 1-7 are patentable over the '966 Patent when taken alone; the '966 Patent in view of *Riikonen* and further in view of *Fabbri*; and the '966 Patent in view of

Riikonen. The Examiner failed to establish a *prima facie* case of obviousness in connection with any of his rejections under 35 U.S.C. § 103(a).

Appellants therefore request that the Examiner be reversed on all of his rejections and the application be remanded for proceedings towards issuance of all of the claims on appeal.

Respectfully submitted,



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Attachment: Claims Appendix

Claims Appendix

1. A method for the treatment of arthritis comprising administering to a subject suffering from arthritis a composition comprising a function blocking antibody or a fragment of said antibody capable of binding an epitope of VLA-1, wherein the epitope consists of the amino acids Val-Gln-Arg-Gly-Gly-Arg (SEQ ID NO:8) or equivalents thereof and wherein the function blocking antibody or a fragment thereof is administered to the subject in a dosage of between about 10 mg to about 250 mg administered over a dosing period of between about one to about seven days to provide a decrease in arthritic score of about 65% or greater when compared to a control antibody treated subject.

2. A method according to claim 1 wherein the decrease in arthritic score is about 79% or greater.

3. A method according to claim 1 wherein the decrease in arthritic score is about 85% or greater.

4. A method according to claim 1 wherein the decrease in arthritic score is about 90% or greater.

5. A method according to claim 1, wherein the antibody is monoclonal.

6. A method according to claim 1, wherein the subject is a human.

7. A method according to claim 1, wherein the subject suffers from rheumatoid arthritis.